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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,431

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,431	Applicant(s) SEKIGUCHI ET AL.	
	Examiner TAMTHOM N. TRUONG	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-30-05 (Preliminary Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Lack of Unity

Applicant's preliminary amendment of 9-30-05 is acknowledged. Claims 1-57 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: claim(s) 1-17 and 52-57 (in part), drawn to compounds of Formula (I), and pharmaceutical composition thereof, wherein:

- a. L represents groups IV, V, VI, VII, VIII, IX, X and XI;
- b. Y is group (i).

Further election of species and/or restriction will be required if this group is elected.

Group II: claim(s) 1 and 52-57 (in part), drawn to compounds of Formula (I), and pharmaceutical composition thereof, wherein:

- a. L represents groups IV, V, VI, VII, VIII, IX, X and XI;
- b. Y is group (ii) or (iii).

Further election of species and/or restriction will be required if this group is elected.

Group III: claim(s) 1, 18-21 and 52-57 (in part), drawn to compounds of Formula (I), and pharmaceutical composition thereof, wherein:

- a. L represents groups IV, V, VI, VII, VIII, IX, X and XI;
- b. Y is group (iv).

Further election of species and/or restriction will be required if this group is elected.

Group IV: claim(s) 1, 23-48 and 52-57, drawn to compounds of Formula (I), and pharmaceutical composition thereof, wherein:

- a. L represents groups XII, XIII or XIV;

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- b. Y is group (i).

Further election of species and/or restriction will be required if this group is elected.

Group V: claim(s) 1 and 52-57 (in part), drawn to compounds of Formula (I), and pharmaceutical composition thereof, wherein:

- a. L represents groups XII, XIII and XIV;
- b. Y is group (ii) or (iii).

Further election of species and/or restriction will be required if this group is elected.

Group VI: claim(s) 1 and 52-57 (in part), drawn to compounds of Formula (I), and pharmaceutical composition thereof, wherein:

- a. L represents groups XII, XIII and XIV;
- b. Y is group (iv).

Further election of species and/or restriction will be required if this group is elected.

Group VII: claim 22, drawn to an intermediate.

Group VIII: claims 49-51, drawn to a method of prophylaxis and treatment for many diseases recited in claim 49. Further election of species and/or restriction will be required if this group is elected.

The inventions of Groups I - VII share a common technical feature of **quinazolinyl** ring, which does not sufficiently define the invention, and is not a contribution to the art. It is the combination of variables L, Y, R₁ and ring Q that gives compounds of each group their unique physical, chemical properties and biological activities. Depending on what they represent, the claimed formula would have different structure. Thus, a reference anticipated or rendered obvious compounds of one group would not do so to those of other groups. Therefore, a separate search is required for each group.

The invention of Group VIII is drawn to a method of treating various diseases which relates to the other groups (I-VII) as a combination-subcombination, and requires additional

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search and examination beyond the scope of the claimed compound. A reference reading on the compounds would not necessarily read on the claimed method. Therefore, the search and examination for all 8 groups would impose a serious burden on the examiner in charge of this invention. Note, a preliminary search in EAST yields a total of 28,025 hits which clearly shows an overwhelming number of references for consideration.

Under 35 U.S.C. 372(b)(2), “international applications designating but not originating in, the United States...the Commissioner may cause the question of unity of invention to be reexamined under section 121 of this title...” Thus, as discussed above, the instant invention clearly lacks unity according to PCT 13.2. Accordingly, restriction under 35 U.S.C. 121 and 372 is deemed necessary.

Rejoinder Criteria: The examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims **will be fully examined for patentability in accordance with 37 CFR 1.104**. Thus, to be allowable, **the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112**. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

9-28-09